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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/076,514	02/19/2002	Ludwig Volkel	52203 3431 EXAMINER	
26474	7590 07/29/2005			
	RUCE DELUCA & (	YOUNG, MICAH PAUL		
SUITE 400	TREET NW EAST	ART UNIT	PAPER NUMBER	
WASHING	TON, DC 20005	1618		
			DATE MAILED: 07/29/2005	

Please find below and/or attached an Office communication concerning this application or proceeding.

	<b>#</b> )						
	Application	No.	Applicant(s)				
<b></b>	10/076,514		VOLKEL ET AL.				
Office Action Summary	Examiner		Art Unit				
	Micah-Paul	Young	1618				
The MAILING DATE of this comm Period for Reply	unication appears on the c	over sheet with the c	correspondence address				
A SHORTENED STATUTORY PERIOD THE MAILING DATE OF THIS COMMU  - Extensions of time may be available under the provisi after SIX (6) MONTHS from the mailing date of this could be supposed to the second of the secon	UNICATION. cons of 37 CFR 1.136(a). In no event ommunication. y (30) days, a reply within the statutor in statutory period will apply and will a apply will, by statute, cause the application of this communication.	i, however, may a reply be tin ory minimum of thirty (30) day expire SIX (6) MONTHS from ation to become ABANDONE	nely filed s will be considered timely. the mailing date of this communication. D (35 U.S.C. § 133).				
Status							
1) Responsive to communication(s)	filed on 03 May 2005.						
2a)⊠ This action is FINAL.							
3) Since this application is in condition	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is						
closed in accordance with the pra	closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.						
Disposition of Claims							
4) ⊠ Claim(s) <u>1,2,4-8 and 10-22</u> is/are 4a) Of the above claim(s) is 5) □ Claim(s) is/are allowed. 6) ⊠ Claim(s) <u>1,2,4-8 and 10-22</u> is/are 7) □ Claim(s) is/are objected to 8) □ Claim(s) are subject to res	s/are withdrawn from cons rejected.	sideration.					
Application Papers							
9)☐ The specification is objected to by	the Examiner.	,					
10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.							
Applicant may not request that any of		•	, <b>,</b>				
Replacement drawing sheet(s) includ 11) The oath or declaration is objected	-		• • • • • • • • • • • • • • • • • • • •				
Priority under 35 U.S.C. § 119							
12) Acknowledgment is made of a clai  a) All b) Some * c) None of  1. Certified copies of the prior  2. Certified copies of the prior  3. Copies of the certified copie  application from the Interna  * See the attached detailed Office ac	: ity documents have been ity documents have been es of the priority documen tional Bureau (PCT Rule	received. received in Applicati ts have been receive 17.2(a)).	on No ed in this National Stage				
Attachment(s)							
<ol> <li>Notice of References Cited (PTO-892)</li> <li>Notice of Draftsperson's Patent Drawing Review</li> </ol>	(PTO-948)	) Interview Summary Paper No(s)/Mail Da					
3) Information Disclosure Statement(s) (PTO-1449 Paper No(s)/Mail Date		) Notice of Informal P	atent Application (PTO-152)				

Application/Control Number: 10/076,514

Art Unit: 1618

#### **DETAILED ACTION**

Acknowledgment of Papers Received: Amendment/Remarks dated 5/3/05.

# Claim Rejections - 35 USC § 103

- 1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 2. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
  - 1. Determining the scope and contents of the prior art.
  - 2. Ascertaining the differences between the prior art and the claims at issue.
  - 3. Resolving the level of ordinary skill in the pertinent art.
  - 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
- 3. Claims 1,2,4-8,and 10-22 rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Spires (USPN 4,394,377 hereafter '377) and Klein et al (UPSN 2,870,198 hereafter '198). The claims are drawn to a choline ascorbate formulation. The choline ascorbate is incorporated into a feed composition for ruminant animals.
- 4. The '377 discloses a feed for ruminant animals 'comprising crystalline choline salts made with organic and inorganic acids (abstract). According to '377, the crystalline salts including choline ascorbate are available commercially (col. 3, lin. 62 col. 4, lin. 7). The crystals can be incorporated into ruminant animal supplement (col. 4, lin. 28 35, col. 14, lin. 4-13). '377 further discloses that organic solvents such as methanol and ethylene oxide are common within

the production of choline ascorbate (col. 3, lin. 49-55). This process of crystallization is well known in the art and can be seen in '198.

- 5. The '198 patent teaches the crystallization of choline salts (abstract). Isolation with ethylene oxide and trimethylamine, at low temperature (below  $40^{\circ}$ C) is well known in the art as seen in '198 (col. 2, lin. 18 59). Organic acids such as anhydrous citric acid are used in the reaction (examples). It would be within the level of skill in the art to produce the choline ascorbate of '377 by the process of '198 by substituting ascorbic acid as the organic acid.
- 6. With regard to claims reciting the diffraction characteristics of the compound, it is the position of the examiner that these characteristics would be inherent to the compound recited in the art. Presented here is a crystalline choline ascorbate free from water of crystallization, and processed from reacting ascorbic acid, trimethylamine and ethylene oxide, at a temperature below 40°C. Barring a showing of unexpected results or evidence to the contrary it is the position of the examiner that the compounds of the present invention and the compound recited by the art are identical, hence having identical properties including diffraction characteristics. The diffraction information claimed can be determined through routine experimentation by artisans of ordinary skill and do not impart patentability on the formulation.
- 7. Also the Office does not have the facilities for examining and comparing applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same material structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed products are functionally different than those taught by the prior art and to establish patentable differences. See Ex parte Phillips, 28 U.S.P.Q.2d 1302, 1303 (PTO Bd. Pat. App. &

Art Unit: 1618

Int. 1993), Ex parte Gray, 10 USPQ2d 1922, 1923 (PTO Bd. Pat. App. & Int.) and In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

8. With these things in mind one of ordinary skill in the art would have been motivated to process choline ascorbate as seen in '198 in order to produce stable crystals that are anhydrous and have high levels of purity. It would have been obvious to combine these crystals resulting from the '198 patent with the ruminant animal feed formulations of '377 in order to produce an improved feed formulation. It would have been obvious to combine the teachings of these references in order to provide a feed composition with improved stability and nutritional value.

### Response to Arguments

- 9. Applicant's arguments filed 5/3/05 have been fully considered but they are not persuasive. Applicant argues that:
  - a. The teachings of '377 and '198 do not disclose the formulation of the instant claims.
- 10. Regarding argument a., it is the position of the Examiner that the teaching sand disclosures of the prior art provide sufficient suggestion to obviate the claimed invention. The claims are drawn to a choline ascorbate crystal with specific diffraction lines. Though the prior art is silent to these features, the choline ascorbate is produced in a similar way as that of the instant claims. The crystal is anhydrous and is formed by using organic solvents at low temperatures. The particular solvent can be determined through routine experimentation to determine the solvent combination that results in the best crystals. Barring evidence to the contrary it is the Examiner that the teachings of the organic water-miscible solvents obviates the instant claims. As discussed above the Office does not have the facilities for examining and

Application/Control Number: 10/076,514

Art Unit: 1618

comparing applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same material structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed products are functionally different than those taught by the prior art and to establish patentable differences. *See Ex parte Phillips*, 28 U.S.P.Q.2d 1302, 1303 (PTO Bd. Pat. App. & Int. 1993), *Ex parte Gray*, 10 USPQ2d 1922, 1923 (PTO Bd. Pat. App. & Int.) and *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977). Barring a showing of unexpected results found regarding the particular process claimed, it is the position of the Examiner that the claims remain obviated by the prior art.

## Conclusion

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Art Unit: 1618

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 571-272-0608. The examiner can normally be reached on M-F 7:00-4:30 every other Monday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Micah-Paul Young Examiner Art Unit 1618

MP Young

THURMAN K PAGE SUPERVISORY PATENT FXAMINER TECHNOLOGY CENTER 1800